



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,939	09/28/2005	Ian Hughes	PB60179USw	4596
23347	7590	04/13/2009	EXAMINER	
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			HOBBS, MICHAEL L	
			ART UNIT	PAPER NUMBER
			1797	
			NOTIFICATION DATE	DELIVERY MODE
			04/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM
LAURA.M.MCCULLEN@GSK.COM
JULIE.D.MCFALLS@GSK.COM

Office Action Summary	Application No. 10/550,939	Applicant(s) HUGHES ET AL.	
	Examiner MICHAEL HOBBS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/09/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed on 01/09/2009 has been considered and entered for the record.
2. Applicant's amendment overcomes the claim objection in paragraph 2 and the 35 USC 112 second paragraph rejection of claims 11, 19 and 23 in paragraph 4 of the Office Action mailed on 07/09/2008.
3. Claims 1-18 and 20-22 are pending further examination upon the merits.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 01/09/2009 and has been considered by the examiner.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. On line 7 of claim 1 and on line 2 of claim 4, the applicant claims a "means [is] adapted to vary the physical condition within in or of the channel structure" with no explanation of the means. Furthermore, the means for varying the physical condition

Art Unit: 1797

are not disclosed within the specification and therefore, if the applicant was intending to invoke 35 U.S.C. 112 sixth paragraph, there is insufficient guidance within the specification as to how the physical within the channels are adjusted or varied.

Therefore, one of ordinary skill in the art would not be able to determine what the "means" to "vary the physical conditions" within the channel is and this renders the claims indefinite.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-18, 20 and 21 stand rejected under 35 U.S.C. 102(b) as being anticipated by Parce et al. (US 6,046,056).

10. Parce discloses a high-throughput screening assay system for micro-scale fluidic devices. For claim 1, Parce discloses a micro-fluidic system that is a closed loop system (Fig. 6c) that can be operated on a continuous basis (col. 8 lines 10-12) and is fully capable of being automated. Sensors are used within the device to detect signals from the stream such as chromophoric or fluorescent signals (col. 8 lines 26-28, 61-62). The conditions within the channel can be altered with the addition of a test compound (col. 8 lines 35-36) or by the field generated by an electrical fluid direction system (col. 8

Art Unit: 1797

lines 62-63). The device is connected to computer (col. 22 lines 4-8) which controls the fluid flow through the chambers and analyzes the data (“receive[s] the sensor signal”) from the screening and is fully capable of adjusting the conditions within the channel based on this data.

11. With regards to claims 2 and 3, the sensor sends a signal to the computer as discussed above relating to the fluorescent signal generated from the target molecule (col. 8 lines 26-28). With regards to claim 4, the physical condition within the channel such as fluid flow can be controlled by the computer (col. 22 lines 4-8). Furthermore, the conditions within the channel can be altered with the addition of a test compound (col. 8 lines 35-36) or by the field generated by an electrical fluid direction system (col. 8 lines 62-63) and for claim 5 Parce teaches using micro-pipettors for introducing test compounds or reagents to the device (col. 22 lines 25-26). With regards to claims 6 and 7, Parce discloses a buffer system (720) that fills the plates on a conveyor system (col. 21 lines 61-64) which the computer is fully capable of operating and the test compounds are within a multi-well plate or array (col. 22 lines 28-30).

12. For claim 8, as stated above, the computer is fully capable of controlling the buffer system and the additions of test compounds from the multi-well plates will vary the conditions within the channel. Regarding claim 9, Parce teaches at least two inlets with one inlet “downstream” from another inlet (Fig. 6c). For claim 10, the computer of Parce is fully capable of running the system without intermediate instruction from an operator. With regards to claim 11, the computer of Parce is fully capable of running the reaction within the channel until the “physical property” satisfies a “predetermined

Art Unit: 1797

objective". For claim 12, Parce discloses that the "predetermined property" is the fluorescence of the target solutions as was discussed above. With regards to claim 13, the computer of Parce is fully capable of not controlling conditions within the channel (i.e. the computer is turned off).

13. With regards to claim 14, Parce discloses a chemical property such as a colorimetric or fluorimetric response from the device (col. 10 lines 42-45). Parce discloses for claim 15 that the cellular activity is monitored by the device (col. 4 lines 65-67). For claim 16, Parce teaches that the conditions within the channel can be altered with the addition of a test compound (col. 8 lines 35-36) or by the field generated by an electrical fluid direction system (col. 8 lines 62-63). With regards to claim 17, Parce also discloses controlling the flow rate or geometry of the channel through fabricated fluid direction devices such as pumps and valves (col. 18 lines 16-22). For claim 18, the computer is an integrated part of the system (col. 22 lines 4-8).

14. For claim 20, Parce discloses using a micro-well plate or array with test compounds (col. 22 lines 28-32) with a computer to control the device where each well has a different test compound (col. 2 lines 48-67) through micro-fluidic channels. For claim 21, Parce teaches that the test compounds are identified or categorized (col. 5 lines 17-21) as effective pharmacological agents for the treatment of disease.

15. Therefore, Parce meets the limitations of claims 1-,18, 20 and 21.

Art Unit: 1797

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claim 23 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al. (US 6,046,056).

Art Unit: 1797

20. Parce discloses using the system as discussed above for claim 1(col. 2 lines 48-65) for the high-throughput micro-fluidic system. With regards to claim 23, Parce does not specifically teach that the computer operates the system "heuristically" (learns) or that the "predetermined property" is optimized. However, the use of a computer or algorithm that adjusts the parameters based on feed back from the system is within the skills of one of ordinary skill in the art. Further, Parce implies that the computer optimizes the system for the reaction within the micro-channels where the monitored property is optimized for the target solution being screened by the devices. Therefore, it would be obvious to one of ordinary skill in the art to employ an "intelligent" computer and optimize the reaction based on the teachings of Parce in order to determine which of the samples are contain the most effective pharmacological agents.

Response to Arguments

21. Applicant's arguments filed 12/02/2008 have been fully considered but they are not persuasive. With regards to applicant's argument on page 6 paragraph 1 that the physical condition, such as temperature, can be varied by a heating element and that that the flow of the fluid within the channel can be varied by flow rate controllers that are well-known within the art such as pumps, electroosmotic flow and electrokinetic flow. However, if the applicant was seeking to invoke 35 U.S.C. 112 sixth paragraph with the claim language, the lack of guidance would render the claims indefinite and, furthermore, the claims are indefinite since one of ordinary skill in the art would not have guidance as to how the conditions within the chip are varied and what number or type of

Art Unit: 1797

well-known art elements would meet the limitations of varying the conditions within the channel. Therefore, the 35 U.S.C 112 second rejection of claims 1 and 4 is proper and will stand in this action.

22. With regards to applicant's argument on page 7 paragraph 7 that Pace does not disclose an "automated closed-loop control mechanism", the Examiner disagrees with this assertion. As stated in the previous action, the reaction of Pace can be operated in a continuous fashion which implies that the operation is automated. Therefore, the rejections of claims 1-18 and 20-22 under 35 U.S.C. 102(b) stands.

Conclusion

23. Claims 1-18 and 20-22 are rejected.

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1797

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/M. H./
Examiner, Art Unit 1797